

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Michael O'Connor et al.

Serial No.: 10/729,632

Filed: 12/05/03

Entitled: Controlled Environment Device

Group No.: 3736

Examiner: Veniaminov, N.

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on September 16,2004.

By: Cliff Cannon-Cin

Sir or Madam:

The citations listed below, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

In accordance with 37 C.F.R. §1.98 (d), copies of some of the references listed below are **not** provided since they were previously submitted by Applicants in U.S. Patent Appln. No. 09/972,236, filed on October 5, 2001 (Our File: OCONNOR-06575), now U.S. Patent No. 6,685,622, issued on February 3, 2004, which is relied upon for an earlier filing date under 35 U.S.C. §120. In addition, since the instant application was filed after June 30, 2003, copies of U.S. Patents and published Applications cited in the Information Disclosure Statement are not required and therefore have **not** been provided (MPEP, 609, III A(2)).

The following printed publications are referred to in the body of the specification:

Barazzone et al., "Oxygen toxicity in mouse lung: pathways to cell death," Am.
 J. Respir. Cell Mol. Biol., 19:573-581 [1998];

- Cargnoni et al., Changes in oxidative stress and cellular redox potential during myocardial storage for transplantation: experimental studies," J. Heart Lung Transplant., 18:478-487 [1999];
- Ihnken *et al.*, "Studies of hypoxemic/reoxygenation injury: without aortic clamping," J. Thorac. Cardiovasc. Surg., 110:1171-1181 [1995];

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- Ihnken *et al.*, "Normoxic cardiopulmonary bypass reduces oxidative myocardial damage and nitric oxide during cardiac operations in the adult," J. Thorac. Cardiovasc. Surg., 116:327-334 [1998];
- Knight, "Free radicals: their history and current status in aging and disease,"
 Ann. Clin. Lab. Sci., 28:331-346 [1998];
- Morita et al., "Studies of hypoxemic/reoxygenation injury: without aortic clamping," J. Thorac. Cardiovasc. Surg., 110:1235-1244 [1995];
- Pepper et al., "Sequential oxidative damage, and changes in iron-binding and iron-oxidising plasma antioxidants during cardiopulmonary bypass surgery,"
 Free Rad. Res., 21:377-385 [1994];
- Satoh *et al.*, "Oxygen toxicity induces apoptosis in neuronal cells," Cell. Mol. Neurobiol., 18:649-666 [1998];
- Sellke *et al.*, "Twenty-four-hour heart preservation using continuous cold perfusion and copper (II) complexes," J. Surg. Res., 80:171-176 [1998];
- Tian et al., "Alterations of antioxidant enzymes and oxidative damage to macromolecules in different organs or rats during aging," Free Radical Biol. Med., 24:1477-1484 [1998]; and
- Williams *et al.*, "Postoperative lung injury and oxidative damage in patients undergoing pulmonary resection," Eur. Respir. J., 11:1028-1034 [1998].

Also, Applicants have become aware of the following printed publications, which may be material to the examination of this application:

- U.S. Patent No. 4,262,091 to Cox [1981];
- Capellier *et al.*, "Oxygen tolerance in patients with acute respiratory failure," Intensive Care Med 24:422-428 [1998];

- Folz et al., "Extracellular superoxide dismutase in the airways of transgenic mice reduces inflammation and attenuates lung toxicity following hyperoxia," J. Clin. Invest. 103:1055-1066 [1999];
- Fridovich, "Oxygen toxicity: a radical explanation," J. Exp. Biol. 201:1203-1209 [1998];
- Ihnken *et al.*, "Studies of hypoxemic/reoxygenation injury:without aortic clamping," J. Thorac. Cardiovasc. Surg., 110:1182-1189 [1995];
- Ihnken, "Hyperoxic cardiopulmonary bypass causes reoxygenation injury and lipid peroxidation," J. Thorac. Cardiovasc. Surg., 114:304-305 [1997];
- Oldham and Bowen, "Oxidative stress in critical care: is antioxidant supplementation beneficial?" J. Am. Diet. Assoc. 98:1001-1008 [1998]; and
- Novelli *et al.*, "Vitamin E protects human skeletal muscle from damage during surgical ischemia-reperfusion," Am. J. Surg. 172:206-209 [1996].

In addition, the Examiner has cited the following patents in the Office Action mailed June 16, 2004:

- U.S. Patent No. 4,026,286 to Trexler [1977];
- U.S. Patent No. 4,059,903 to Piet et al. [1977];
- U.S. Patent No. 4,089,571 to Landy [1978];
- U.S. Patent No. 4,111,753 to Folsom *et al.* [1978];
- U.S. Patent No. 4,566,293 to Arner *et al.* [1986];
- U.S. Patent No. 4,612,916 to Akers et al. [1986];
- U.S. Patent No. 4,950,222 to Scott et al. [1990];
- U.S. Patent No. 4,960,143 to Dore Jr., et al. [1990];
- U.S. Patent No. 5,380,077 to Puschner et al. [1995]; and
- U.S. Patent No. 5,636,643 to Argenta *et al.* [1997].

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material

PATENT Attorney Docket No. OCONNOR-07998

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to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: September 16, 2004

Christine A. Lekutis Registration No. 51,934

MEDLEN & CARROLL, LLP 101 Howard Street, Suite 350 San Francisco, California 94105 415/904-6500

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FORM PTO-14 (Modified)	449	Ten sever	U.S. Department of Commerce Patent and Trademark Office Attorney Docket No.: OCONNOR-07998			Serial No.: 10/729,632				
INFO	RMATI	ON DISCLOSURE ST (Use Several Sheets		Applicant: Michael O'Connor et al.						
(37 CFR § 1.98(b))					Filing Date: 12/05/2	Group Art Unit: 3736				
				U.S. PATENT DOC	UMENTS				_	
Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee		Class	Subclass	Filing	Date	
	1	4,026,286	05/31/77	Trexler Piet et al. Landy Folsom et al. Cox Arner et al. Akers et al.						
	2	4,059,903	11/29/77							
	3	4,089,571	05/16/78							
	4	4,111,753	09/05/78							
	5	4,262,091	04/14/81							
	6	4,566,293	01/28/86							
	7	4,612,916	09/23/86							
	8	4,950,222	08/21/90	Sc	ott <i>et al</i> .					
	9	4,960,143	10/02/90	Dore	Jr. , et al.					
	10	5,380,077	01/10/95	Pusc	hner <i>et al</i> .					
	11	5,636,643	06/10/97	Arg	enta <i>et al</i> .					
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		Document					0.1.1	Translation		
		Number	Publication Date	Country	/ Patent Office	Class	Subclass	Yes	No	
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		OTHER I	DOCUMENTS (Inclu	ding Author, Title, D	ate, Relevant Pages, Pla	ace of Publication)				
	12	Barazzone et al., "Oxygen toxicity in mouse lung: pathways to cell death," Am. J. Respir. Cell Mol. Biol., 19:573-581 [1998]								
	13	Cargnoni et al., Changes in oxidative stress and cellular redox potential during myocardial storage for transplantation: experimental studies," J. Heart Lung Transplant., 18:478-487 [1999]								
	14	Ihnken et al., "Studies of hypoxemic/reoxygenation injury: without aortic clamping," J. Thorac. Cardiovasc. Surg., 110:1171-1181 [1995]								
	15	Ihnken et al., "Normoxic cardiopulmonary bypass reduces oxidative myocardial damage and nitric oxide during cardiac operations in the adult," J. Thorac. Cardiovasc. Surg., 116:327-334 [1998]								
	16	Knight, "Free radicals: their history and current status in aging and disease," Ann. Clin. Lab. Sci., 28:331-346 [1998]								
	17	Morita et al., "Studies of hypoxemic/reoxygenation injury: without aortic clamping," J. Thorac. Cardiovasc. Surg., 110:1235-1244 [1995]								
	18	Pepper et al., "Sequential oxidative damage, and changes in iron-binding and iron-oxidising plasma antioxidants during cardiopulmonary bypass surgery," Free Rad. Res., 21:377-385 [1994]								
	19	Satoh et al., "Oxyge	Satoh et al., "Oxygen toxicity induces apoptosis in neuronal cells," Cell. Mol. Neurobiol., 18:649-666 [1998]							
	20	Sellke et al., "Twenty-four-hour heart preservation using continuous cold perfusion and copper (II) complexes," J. Surg. Res., 80:171-176 [1998]								
	21	Tian et al., "Alterations of antioxidant enzymes and oxidative damage to macromolecules in different organs or rats during aging," Free Radical Biol. Med., 24:1477-1484 [1998]						ree		
	22	Williams et al., "Postoperative lung injury and oxidative damage in patients undergoing pulmonary resection," Eur. Respir. J., 11:1028-10 [1998]							28-103	
	23	Capellier et al., "Ox	Capellier et al., "Oxygen tolerance in patients with acute respiratory failure," Intensive Care Med 24:422-428 [1998]							
	24	Folz et al., "Extrace following hyperoxia	Folz et al., "Extracellular superoxide dismutase in the airways of transgenic mice reduces inflammation and attenuates lung toxicity following hyperoxia," J. Clin. Invest. 103:1055-1066 [1999]							
	25	Fridovich, "Oxygen	toxicity: a radical ex	planation," J. Exp. B	iol. 201:1203-1209 [199	98]				
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FORM PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: OCONNOR-07998	Serial No.: 10/729,632					
INFORM	ATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)	Applicant: Michael O'Connor et al.						
(37 CFR § 1.98(b))		Filing Date: 12/05/03	Group Art Unit: 3736					
OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)								
2	26 Ihnken et al., "Studies of hypoxemic/reoxygenation injury:without aortic clamping," J. Thorac. Cardiovasc. Surg., 110:1182-1189 [1995]							
2	Ihnken, "Hyperoxic cardiopulmonary bypass causes reoxyge [1997]	ation injury and lipid peroxidation," J. Thorac. Cardiovasc. Surg., 114:304-305						
2	Oldham and Bowen, "Oxidative stress in critical care: is an	xidant supplementation beneficial?" J. Am. Diet. Assoc. 98:1001-1008 [1998]						
2	Novelli <i>et al.</i> , "Vitamin E protects human skeletal muscle fi [1996]	ovelli et al., "Vitamin E protects human skeletal muscle from damage during surgical ischemia-reperfusion," Am. J. Surg. 172:206-209						

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